I. REMARKS

Claims 3, 5 to 7, 9, 10, and 12 to 20 are pending. No claims are amended, withdrawn, added, or canceled. The Applicant thanks the Examiner for stating that the written description and prior art rejections are withdrawn. Office Action at page 30.

1. Claim Rejection under 35 U.S.C. § 101:

Claims 3, 5 to 7, 9, 10, and 12 to 20 were rejected under 35 U.S.C. § 101, because the claimed invention allegedly "lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." *Id.* at page 5. The Examiner admits that the specification discloses many uses for the claimed invention. However, the Examiner states that "(n)one of these asserted utilities are specific because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid and therefore not particular to the nucleic acid sequence claimed." *Id.* at page 6. The Applicant respectfully traverses this rejection.

One use of the elected SEQ ID NO: 1 can be shown by a BLASTN analysis. A BLASTN analysis is a well-known and conventional technique that can be used to obtain information on nucleic acid sequences. *See, for example*, Specification at page 5. One result from a BLASTN analysis of the claimed SEQ ID NO: 1 is shown below. As these results show, the claimed nucleotide sequence shows 95 percent identity to a sequence obtained from *Glycine max* (soybean).

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> gb|CF921918.1| U gmrhRww24-04-T7_H11_1_081 Soybean root hair subtracted
cDNA library gmrhRww24 Glycine max cDNA, mRNA sequence.
Length=611
 Score =  168 bits (85),  Expect = 8e-39
 Identities = 100/105 (95%), Gaps = 0/105 (0%)
 Strand=Plus/Minus
```

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Query  238  AGGTACTCTACCCATTTTGCATGCCTCTTGGTTAACTTGCTTTGCCCTCTAATGTACTTA  297
            ||||||||||||||||||||||||| ||| |||||||||||| ||||||||||||||||
Sbjct  595  AGGTACTCTACCCATTTTGCATGCCTTTTGTTTAACTTGCTTTTCCCTCTAATGTACTTA  536
Query  298  AGTGATTGATGATCACTATGAATGACAAATTCCTTGGAAACAAGG  342
            |||||||| ||||||||||||||||||||||||| ||||||||
Sbjct  535  AGTGATTGGTGATCACTATGAATGACAAATTCCTTGCAAACAAGG  491
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This sequence was obtained by Scheffler, B.E., Huang, S., Liu, X., Nguyen, H., Duke, M. and Stacey, G. in an unpublished work entitled "Expressed sequence tags from soybean root hair subtractive cDNA library." The cDNA clones were generated from soybean root hair tissue treated with *Bradyrhizobium japonicum* for 24 hours. All information above is readily available from conducting the BLASTN analysis of SEQ ID NO: 1 through the National Center of Biotechnology Information (NCBI) website.

In other words, SEQ ID NO: 1 has utilities specific to it and not generally applicable to any nucleic acid. For instance, SEQ ID NO: 1 can be used to isolate genes, map genes, and determine gene function associated with nitrogen fixation because it is well known to one of ordinary skill in the art that *B. japonicum* is a gram negative, nitrogen-fixing bacterium belonging to the Rhizobiaceae family. *B. japonicum* and *Glycine max* have a symbiotic relationship and *B. japonicum* helps *Glycine max* fix nitrogen, *i.e.*, convert nitrogen gas into a form readily utilized by the plant. The result of this symbiosis is a dramatic increase in plant production without the need for adding external fertilizer. In other words, the utilities associated with SEQ ID NO: 1 are credible, substantial, and well-established; they are neither vague nor impractical. The Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and has done so in the present case.

The Applicant respectfully reminds the Examiner that the utilities disclosed in the specification must be accepted as factually sound unless the USPTO cites information that

undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the Examiner is aware, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The BLASTN analysis provides such a reasonable correlation through sequence identity: a 95 percent identity to a gene sequence associated with nitrogen fixation obtained from *Glycine max* is a reasonable correlation.

The Examiner states that "(i)t has not been demonstrated that SEQ ID NO: 1 has any utility as a marker for a specific phenotypic trait." Office Action at page 11. The Applicant has shown above that this is incorrect. The Examiner also states that some of the utilities disclosed by the specification "conflict with one another" because "if SEQ ID NO: 1 is a promoter or contains a promoter, it is not a coding portion of a gene. *Id.* at pages 11 to 12. This is also an incorrect statement because SEQ ID NO:1 is a STC and, as the specification makes clear, "STCs can represent a copy of up to a full length of a mRNA transcript, a promoter element or part of a promoter, can contain simple sequence repeats (also called microsatellites) repetitive elements or fragments of repetitive elements, other DNA markers, or any combination thereof." Specification at pages 1 to 2 (emphasis added). In other words, a particular sequence may contain both promoter regions and gene coding regions– neither of which would conflict with the

other. Such a sequence could have utility as both a promoter and in identifying specific genetic traits.

In conclusion, because the Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and has done so with sufficient specificity and reasonable correlation in the present application, the rejection under 35 U.S.C. § 101 is incorrect and the Applicant respectfully requests its withdrawal.

2. Claim Rejections under 35 U.S.C. § 112, first paragraph:

Claims 3, 5 to 7, 9, 10, and 12 to 20 were rejected under 35 U.S.C. § 112, first paragraph, allegedly "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility ..., one skilled in the art clearly would not know how to use the claimed invention." Office Action at page 13. The Applicant respectfully traverses this rejection and contends that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101.

Claims 3, 5, 6, 7, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 20 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for "failing to comply with the enablement requirement." Office Action at page 14. The Applicant respectfully traverses this rejection.

As an initial matter, the Applicant acknowledges that the Examiner has not rejected claim 10 as failing to comply with the enablement requirement. As a result, the Applicant submits that *at a minimum*, claim 10 fully satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

With respect to claims 3, 5, 6, 7, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 20, the Applicant respectfully submits that the specification as filed fully enables these claims as well. The

Applicant reiterates that performing routine and well-known steps, such as sequence alignment protocols, construct preparation, and gene expression analysis, cannot create undue experimentation even if the steps are laborious. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). The Examiner states that the present application differs from *In re Angstadt* because "not a single working example of a construct which comprises SEQ ID NO: 1 within a promoter that functions as set forth in the claims or any other enabled utility for SEQ ID NO: 1 is provided." Office Action at page 29.

The Applicant respectfully reminds the Examiner that the presence or absence of an example cannot be the basis for an enablement rejection under 35 U.S.C. § 112, first paragraph. M.P.E.P. § 2164.02 states:

> 2164.02 Working Example
>
> Compliance with the enablement requirement of 35 U.S.C. 112 first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.
>
> An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).
>
> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).
>
> Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But because only an enabling disclosure is required, applicant need not describe all actual embodiments.

The Applicant respectfully submits that the art is not unpredictable and undeveloped as alleged by the Examiner. For example, the Examiner states that "(t)here is no way to predict how one could change hundreds of nucleotides within SEQ ID NO: 1 and still arrive at a molecule that has any similar function to SEQ ID NO: 1, whether it be a partial promoter function or enhancer function or encoding structural gene function." Office Action at page 30.

Firstly SEQ ID NO: 1 is 394 nucleotides long and a molecule that has 70% identity to SEQ ID NO: 1 (the lowest limit claimed) would involved *at most* a change of 118 nucleotides – not hundreds as the Examiner alleges. Second, this number vastly over-counts the number of possible changes because, as the specification makes clear (and as one of ordinary skill in the art is aware), conservative nucleic acid substitutions generally retain functionality while non-conservative substitutions generally do not. *See, for example*, Specification at pages 26 and 27. In other words, one of ordinary skill in the art would not make many of the possible 118 nucleotide changes. Third, one of ordinary skill in the art would know, or be able to predict, how each of the possible 118 nucleotide changes would affect SEQ ID NO: 1. In other words, the Examiner's statement that "there was no way to predict which changes could be made to the sequence without abolishing function" is incorrect. Office Action at page 30. If one of ordinary skill in the art can reasonably predict, without undue experimentation, what the effects of changes would be, *i.e.*, which would be successes and which would be failures, the claim is enabled through its entire scope. *See, for example, Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984).

In conclusion the Applicant respectfully submits that the art is not unpredictable even with respect to a molecule that has 70% identity with SEQ ID NO:1 and is even more predictable

as the percent identity increases. Stated differently, the specification as filed fully enables claims 3, 5, 6, 7, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 20. Therefore, the Applicant respectfully requests withdrawal of the rejection of claims 3, 5, 6, 7, 9, 12, 13, 14, 15, 16, 17, 18, 19, and 20 as not being enabled under 35 U.S.C. § 112, first paragraph.

3. Claim Rejections under 35 U.S.C. § 112, first paragraph (written description) and 35 U.S.C. § 102(b):

Claims 12, 13, 14, 15, 17, 18, and 19 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for "failing to comply with the written requirement." Office Action at page 20. Claims 3, 5, 6, 7, 9, and 10 to 19 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tanksley *et al.* (U.S. Pat. No. 5,648,599). *Id.* at page 25. Claims 10 to 20 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Stratagene Catalog (1997, p. 95). *Id.* at page 26.

As an initial matter, the Applicant is puzzled by the inclusion of these rejections because the Examiner stated that:

- "This action differs from the previous office action because the rejections for lack of written description and under 102(b) are deleted in this office action." *Id.* at page 2.
- "The inclusion of these rejections in the office action mailed 9/15/06 was an editing error." *Id.*
- "This office action represents a complete office action." *Id.* and
- "The written description and prior art rejections are WITHDRAWN, the first in view of applicant's remarks and the second in view of the amendments to the claims." *Id.* at page 30.

Based on these statements, the Applicant is clear that the inclusion of the rejections for lack of written description under 35 U.S.C. § 112, first paragraph, and prior art under 35 U.S.C. § 102(b) in the Office Action of September 15, 2006 was in error. However, the Applicant is unclear as to whether the reiteration of the rejections for lack of written description under 35 U.S.C. § 112, first paragraph, and prior art under 35 U.S.C. § 102(b) in the present Office Action, coupled with the statements that "(t)his office action represents a complete office action" and "(t)he written description and prior art rejections are WITHDRAWN, the first in view of applicant's remarks and the second in view of the amendments to the claims" means that these rejections are still pending.

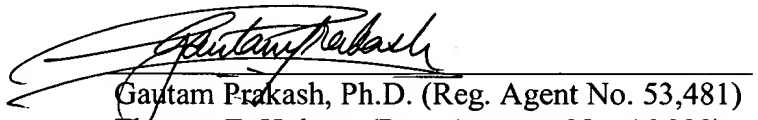
If these rejections are still pending, the Applicant respectfully traverses them and contends that they have been overcome and/or rendered moot by the arguments and amendments set forth above in the Applicant's response filed July 6, 2006. For efficiency and brevity reasons, the Applicant does not reiterate the arguments and amendments set forth above in the Applicant's response filed July 6, 2006. Instead, the Applicant hereby incorporates his response filed July 6, 2006 in its entirety.

III. CONCLUSION

In view of the foregoing remarks, the Applicant respectfully submits that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

Date: January 30, 2007



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